

**REMARKS**

Claims 1, 3-7 and 9-11 are pending and under consideration. Claim 1 has been amended to incorporate the elements of claims 4 and 5, which have been cancelled without prejudice. Upon entry of the amendments, claims 1, 3, 6, 7 and 9-11 will be pending and under examination. The amendments do not add any new matter and entry is respectfully requested.

**Regarding 35 U.S.C. § 112, First Paragraph (Enablement)**

Applicants respectfully traverse the rejection of claims 1 and 3 and 6-7 under 35 U.S.C. 112, first paragraph, as allegedly containing subject matter not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention.

Essentially, the Office contends that the claimed method of detecting Graves' disease in a human patient is enabled only for measuring the levels of RANTES or IL-16 or by measuring fibroblast activation. While Applicant respectfully maintain that the specification enables the full scope of the claimed invention, base claim 1 has been amended to recite the embodiments indicated in the Office Action to be enabled, rendering moot the rejection. Accordingly, Applicants respectfully request removal of the rejection of claims 1 and 3 and 6-7 under 35 U.S.C. 112, first paragraph, as allegedly containing subject matter not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention.

**Regarding 35 U.S.C. § 112, First Paragraph (Written Description)**

Applicants respectfully traverse the rejection under 35 U.S.C. §112, first paragraph, for allegedly containing subject matter not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention of claims 1 and 3 and 6-7.

Essentially, the Office contends that the claims are sufficiently described only for a method of detecting Graves' disease in a human patient that encompasses measuring the levels of RANTES or IL-16 or by measuring fibroblast activation. While Applicant respectfully maintain that the specification provides written description for the claimed invention, base claim 1 has been amended to recite the embodiments indicated in the Office Action to be sufficiently disclosed, rendering moot the rejection. Accordingly, Applicants respectfully request removal of the rejection under 35 U.S.C. 112, first paragraph, as allegedly containing subject matter not

described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention of claims 1 and 3-11.

**Regarding 35 U.S.C. § 102**

Applicants respectfully traverse the rejection of claims 1-3 and 7-8 under 35 U.S.C. § 102(a) as allegedly being anticipated by Kendall-Taylor et al., *Journal of Endocrinology* (1990). Applicants respectfully submit that this rejection has been rendered moot by incorporation of the elements of non-rejected claims 4 and 5 into base claim 1. Accordingly, Applicants respectfully request removal of the rejection of claims 1, 3 and 7-8 under 35 U.S.C. § 102(a) as allegedly being anticipated by Kendall-Taylor et al., *Journal of Endocrinology* (1990).

Applicants respectfully traverse the rejection of claims 1, 3 and 7-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Rotella et al., *J. Clin. Endocrinol. Metabol.* (1986) 62:357-367. Applicants respectfully submit that this rejection has been rendered moot by incorporation of the elements of non-rejected claims 4 and 5 into base claim 1. Accordingly, Applicants respectfully request removal of the rejection of claims 1, 3 and 7-8 under 35 U.S.C. § 102(a) as allegedly being anticipated by Rotella et al.

**Regarding 35 U.S.C. § 103**

Applicants respectfully traverse the rejection of claims 1, 3 and 7 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Weightman et al., *Journal of Endocrinology* (1993). Applicants respectfully submit that this rejection has been rendered moot by incorporation of the elements of non-rejected claims 4 and 5 into base claim 1. Accordingly, Applicants respectfully request removal of the rejection of claims 1, 3 and 7 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Weightman et al., *Journal of Endocrinology* (1993).

Applicants respectfully traverse the rejection of claims 1, 3-7 and 9-11 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Rotella et al., *J. Clin. Endocrinol. Metabol.* (1986) 62:357-367 in view of Sciaky et al. and Urn et al.

Rotella et al. describes an assay for measuring the activity of autoantibodies active in causing ophthalmopathy and concludes that some but not all *TSH receptor* monoclonal antibodies have been found to duplicate the action of the autoimmune IgGs from the

ophthalmopathy patients. Neither Sciaky et al. nor Urn et al. cure the deficiencies of Rotella et al. In particular, the combination of Rotella et al. in view of Sciaky et al. and Urn et al., does not teach or suggest the method of detecting Graves' disease in a patient by obtaining an orbital or skin sample including fibroblasts from the patient, and detecting the activation of fibroblasts by binding of disease specific IgG to the IGF-1 receptor (IGF-1R) relative to a control wherein an increased presence of IgG-activated fibroblasts compared to the control indicates Graves' disease, and wherein fibroblast activation is determined by measuring the level of IL-16 expressed by said IgG-activated fibroblasts, RANTES expressed by said IgG-activated fibroblasts or by measuring T cell migration towards said fibroblasts in said orbital or skin sample.

Accordingly, Applicants respectfully request removal of the rejection of claims 1 and 3-7 and 9-11 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Rotella et al. in view of Sciaky et al. and Urn et al.

### **CONCLUSION**

In light of the amendments and remarks herein, Applicants submit that the claims are now in condition for allowance and respectfully request a notice to this effect. The Examiner is invited to call the undersigned attorney if there are any questions.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502624 and please credit any excess fees to such deposit account.

Respectfully submitted,

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